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CARRIER AND SPECIMEN-HANDLING TOOL FOR USE IN DIAGNOSTIC TESTING

The present invention relates generally to specimen-handling tools and carriers for use in diagnostic testing.

In the medical arena, diagnostic testing is frequently performed to determine if a particular medical condition is present in a given patient. Diagnostic testing systems, which may be referred to as test kits, are manufactured to test for a wide variety of conditions in numerous types of biological test specimens, such as, for example, blood, tissue biopsies, and saliva. Such testing systems may be utilized to determine the presence of particular bacteria, such as *Helicobacter pylori*. Some tests that have been proposed to detect *Helicobacter pylori* include those that are disclosed in numerous U.S. Patents, including, for example, U.S. Patent No. 4,748,113 to Marshall, U.S. Patent No. 5,314,804 to Boguslaski et al., U.S. Patent No. 5,439,801 to Jackson, U.S. Patent No. 5,702,911 to Whalen, U.S. Patent No. 5,989,840 to D'Angelo et al., U.S. Patent No. 6,068,985 to Cripps et al., U.S. Patent No. 6,156,346 to Chen et al., and U.S. Patent No. 6,187,556 to Lee et al., each of such patents being incorporated in their entirety by reference herein.

Particular embodiments of the present invention relate to a specimen-handling tool for use with a diagnostic test kit that includes an elongated body having a longitudinal axis that extends along the length of the elongated body, a first end and a second end. The first end may include an outermost portion that is

adapted to manipulate a tissue biopsy specimen. The outermost portion may be formed as a truncated crescent so that the tip of the truncated crescent is not aligned with the longitudinal axis of the elongated body. The first end may also include an upper surface and a lower surface that is generally inclined toward the upper surface. The upper surface may be generally inclined toward the lower surface in selected embodiments.

The second end of the specimen-handling tool may include a curved upper surface. The specimen-handling tool may also include a gripping portion that may be disposed between the first end and the second end, and the gripping portion may include at least one rib.

The specimen-handling tool may include, in selected embodiments, an elongated body having a longitudinal axis that extends along the length of the elongated body, a first end and a second end. The first end may include an outermost portion, an upper surface, and a lower surface, the upper surface being generally inclined toward the lower surface, the outermost portion being formed as a truncated crescent. The second end may include a concavely curved upper surface.

A gripping portion may be positioned between the first end and the second end of the elongated body, and the gripping portion may include at least one rib. The elongated body may be roughly cylindrical in shape.

The present invention also relates to a diagnostic system that includes a carrier having at least one well, an upper surface, and a cavity extending downwardly from the upper surface. A specimen-handling tool may be configured to be positioned within the cavity and may include an elongated body having a longitudinal axis that extends along the length of the elongated body, a first end comprising an outermost portion adapted to manipulate a tissue biopsy specimen. The carrier may have at least two wells, and one of the wells of the carrier may be D-shaped. The specimen-handling tool and/or carrier may be formed of a rigid plastic such as, for example, polycarbonate.

Figure 1 is a perspective view of an embodiment of the system of the present invention.

Figure 2 is a perspective view of an embodiment of the carrier of the present invention.

Figure 3 is a perspective view of the bottom of an embodiment of the carrier of the present invention.

Figure 4 is a side view of an embodiment of the carrier of the present invention.

Figure 5 is an end view of an embodiment of the carrier of the present invention.

Figure 6 is a perspective view of another embodiment of the system of the present invention.

Figure 7 is a perspective view of an embodiment of the specimen-handling tool of the present invention.

Figure 8 is another perspective view of the embodiment of the specimen-handling tool depicted in Figure 7.

Figure 9 is side view of the embodiment of the specimen-handling tool depicted in Figure 7.

Figure 10 is top view of the embodiment of the specimen-handling tool depicted in Figure 7.

Figure 11 is a perspective view of another embodiment of the specimen-handling tool of the present invention.

Figure 12 is another perspective view of the embodiment of the specimen-handling tool depicted in Figure 11.

Figure 13 is side view of the embodiment of the specimen-handling tool depicted in Figure 11.

Figure 14 is top view of the embodiment of the specimen-handling tool depicted in Figure 11.

Figure 15 is a perspective view of yet another embodiment of the specimen-handling tool of the present invention.

Figure 16 is another perspective view of the embodiment of the specimen-handling tool depicted in Figure 15.

Figure 17 is side view of the embodiment of the specimen-handling tool depicted in Figure 15.

Figure 18 is top view of the embodiment of the specimen-handling tool depicted in Figure 15.

Figure 1 discloses an embodiment of a diagnostic system 20 according to the present invention that may be utilized for many types of diagnostic testing. Such diagnostic tests utilize a biological test specimen such as, for example, tissue biopsy, blood or saliva. The diagnostic system 20 may include a carrier 22 and a mechanism by which a user may manipulate a sample of tissue, such as, for example, the specimen-handling tool 24 that is shown in Figures 1 and 6-18.

As shown in Figures 1-3, the carrier 22 may include a first well 26 and a second well 28. As shown in Figure 6, selected embodiments of the carrier 22 may include a single well 26. The wells 26 and 28 may be defined, at least in part, by the walls 27 and 29, respectively. The wells 26 and 28 may be formed to have a variety of different configurations, such as, for example, frustoconical, cylindrical, or other configurations. As shown in Figures 1-3, the wells 26 and/or 28, when viewed from the top of the carrier 22, are generally D-shaped. The wells 26 and/or 28 may be formed so that, when viewed from the top of the carrier 22, the wells 26 and/or 28 have any of a variety of shapes, such as, for example, elliptical, square, rectangular, or circular. The wells 26 and 28 of the carrier 22 may have similar configurations or dissimilar configurations.

The carrier 22 may have many different overall exterior shapes, such as, for example, the generally rectangular shape as shown in Figures 1-4 and 6. The carrier 22 may be alternately shaped, such as, for example, square, oblong, triangular, and the like. The carrier 22 may, as shown in Figures 2, 3 and 6, include two elongated sides 38, two ends 40 and a surface 44. The ends 40 may be configured to be easily grasped by a user and one, none or both of the ends 40 may include an arcuate portion 42 as shown in Figures 1, 2, 3 and 6.

As shown in Figures 1, 2, 5 and 6, the carrier 22 may include a surface 44. The first and/or second wells 26 and 28, respectively, may be configured to extend downwardly from the surface 44. As shown in Figures 1 and 2, the carrier 22 may also include a cavity 30. At least a portion of the cavity 30 may be formed by the wall 31. The cavity 30 may be configured to extend downwardly from the surface 44, as shown in Figures 1, 2, 3 and 6. In other embodiments, one or both of the wells 26 and 28 and/or the cavity 30 may be formed so as to extend upwardly from at least a portion of the surface 44.

A mechanism by which a user may manipulate a sample of tissue, such as, for example, the specimen handling tool 24 such as that shown in Figures 1 and 6-18, may also be included in particular embodiments of the diagnostic system 20 of the present invention. The specimen-handling tool 24 may be disposed within the cavity 30. In particular embodiments, the specimen-handling tool 24 may be removably attached to the carrier 22 by one or more locking arms, adhesive, or the like.

As shown in Figures 2-6, one or more rails 46 may be included in selected embodiments of the present invention and may be disposed on the carrier 22 so that the rails extend upwardly along at least a portion of the surface 44. In some embodiments, one or more rails 46 may also be configured to extend outwardly from the carrier 22.

As shown in Figures 2-6, one or more supports 50 may be provided which extend downwardly from the surface 44. As seen in Figure 3, the supports 50 permit the carrier 22 to rest in a stable position on a horizontal or other surface. The rails 46 and the supports 50 may be configured to enable the carrier 22 to be automatically processed through a variety of equipment.

If desired, the surface 44 may be configured so that various indicia, such as letters, numbers, symbols and other characters, may be placed onto or formed into the surface 44. For example, and as shown in Figure 2, each well 26 and/or 28 may be given a particular designation, such as A or B, and that designation may be printed or otherwise positioned upon the surface 44.

The carrier 22 may be formed from a variety of materials, including, for example, polycarbonate, polystyrene, polypropylene, polyethylene, polyvinylchloride, or any other type of polyolefin.

Particular embodiments of the specimen-handling tool 24 are shown in Figures 1, 6, and 7-18. The specimen-handling tool 24 may be configured to assist the user in accomplishing particular tasks, such as, for example, manipulating a specimen. The specimen-handling tool 24 may, in some embodiments and as shown in Figures 7-18, include a first end 58 and a second end 60 disposed at opposing ends of an elongated body 62 is disposed between the first end 58 and the second end 60. A longitudinal axis, as shown in Figure 10, may extend along the length of the elongated body 62.

A gripping portion 64 may be provided along at least a portion of the body 62 to enhance the grippability of the specimen-handling tool 24. The gripping portion 64 may include one or more ribs 54, as seen in Figures 9 and 10.

The first end 58 of the specimen-handling tool 24 is adapted to be at least partially inserted into or manipulate a tissue biopsy specimen. The outermost portion 66 of the first end 58 may be pointed, as shown in Figures 7, 11 and 15.

As shown in Figures 7-10 and 15-18, the outermost portion 66 may be formed as a crescent that extends outwardly from the first end 58. The crescent-shape of the outermost portion 66 results in the tip 72 of the outermost portion being spaced-apart from the longitudinal axis L of the elongated body 62 (see Figures 10 and 18). The tip 72 of the outermost portion 66 may be slightly truncated, as seen in Figures 10 and 18. In other embodiments and as shown in Figures 11-14, the outermost portion 66 may be otherwise formed.

As seen in Figures 9 and 17, the first end 58 may also include an upper surface 68 and a lower surface 70. The upper surface 68 of the first end 58 may be generally inclined toward the lower surface 70. In some embodiments, the upper surface 68 may be arcuate (as shown in Figures 7 and 8) but the upper

surface 68 may also be otherwise configured. The lower surface 70 may also be generally inclined toward the upper surface 68. The lower surface 70 and the upper surface 68 of the outermost portion 66 may be formed so that the outermost portion 66 has a uniform thickness (see Figure 9) or a non-uniform thickness (see Figure 11).

The second end 60 of the specimen-handling tool 24 may be used to support a tissue biopsy specimen. The second end 60 of the specimen-handling tool 24 may, as seen in Figure 7, 15 and 16, include an upper surface 74 that may, in some embodiments, be curved concavely. The second end 60 may also be formed into a spatula-type configuration where the upper surface 74 is approximately flat.

The specimen-handling tool may be formed from a variety of materials, including, for example, plastics including polycarbonate, polystyrene, polypropylene, polyethylene, polyvinylchloride, or any other type of polyolefin.

The invention may be embodied in other specific forms without departing from the scope and spirit of the inventive characteristics thereof. The present embodiments therefore are to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.